Development of Region-Specific Therapeutic Foods and Its effect on Lipid profile of CVD subjects

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Introduction

India has witnessed an alarming rise in the occurrence of heart disease, stroke and diabetes in the past 25 years, the prevalence of heart disease and stroke has increased by over 50% from 1990 to 2016 in India, with an increase observed in every state. The contribution of these diseases to total deaths and disease burden in the country has almost doubled in the past 25 years. Heart disease now is the leading individual cause of disease burden in India, and stroke is the fifth leading cause. (Dinesh, 2018). More than half of the total cardiovascular disease deaths in India in 2016 were in people younger than 70 years. Now day's increased premature CVD complication and deaths in early 30s has increased emergency to work or focus on Prevention and management of CVD risk factor. Vasudevan *et.al* describe the prevalence of high blood pressure (BP) and other cardiovascular disease (CVD) risk factors in children and adolescents enrolled in the 2016-2018 Comprehensive National Nutrition Survey (CNNS) of all 29 states of India. The analysis shows an alarming prevalence of high BP in Indian youth: 35% of 10- to 12-year-olds and 25% of 13- to 19-year-olds had BP in the stage 1 or 2 hypertension range; defined according to 2017 American Academy of Pediatrics cut points. Using 2011 Indian census data, this finding translates to approximately 69 million Indian youth with high BP and possibly other CVD risk factors. Abbas *et. al.,* 2022, reported that individuals from southern Indian states had higher BP than those from the northern Indian states and this shows that there is high possibility of development of CVD case in the south Indians.

Healthy life lost to disability due to Premature CVD may make people to experience poor quality of life (Rector *et al*., 2006). Various physical and emotional symptoms, such as dyspnea, fatigue, edema, difficulty sleeping, depression, and chest pain affiliated with CVD (Zambroski et al., 2005) may limit activities of daily and also affect the Economic condition of individual and increase the dependency on other family member and also increases Hospitalization and treatment cost. Directly affect the Quality of life.

Hence, it is necessary to focus on early diagnosis of CVD risk factor, as it is Life style disease or non-communicable disease. Early detection and prevention and management of CVD risk factors significantly support in prevention or reduction of CVD related death and help productivity of Nation. There are many studies reporting that Intervention of Nutraceutical, which are low cost with no or very limited side effect along with life style correction, dietary management and physical activity significantly helps in reduction of blood pressure & improve cardiovascular health. But Most of the nutraceutical's values should be analysed through large clinical trials to

demonstrate their efficacy and safety profile, in prevention and treatment of CVDS. which has set limited guidelines for the safe and effective use of nutraceuticals for the treatment. when compared to a regimented diet plan and treatment with medication. Henceforth, this project demands to test the efficacy of Nutraceuticals along with Nutrition education Intervention with Objective.

1. To screen and document regional foods of anti-lipidemic property
2. To modify traditional food products by incorporating foods of anti-lipidemic property
3. To study the effect of developed therpaeutic products on lipid profile of study subjects
4. To develop an educational package for holistic management of CVD

Review of Literature

Premila *et al*., 2021, concluded that, Caloric restriction and lifestyle change, nutraceuticals such as berberine, resveratrol, quercetin, and L-carnitine have demonstrated CR properties have synergic effect on Managing the CVD and Diabetics.

According to Mudhi *et al.* 2021, Nutraceuticals have proven efficacy in numerous diseases, including cancer, rheumatism, diabetes, and other chronic diseases. The use of scientifically and medically approved nutraceuticals can definitely improve health and prevent certain diseases, and some have exhibited the same efficacy as that of conventional pharmaceuticals. Generally, nutraceuticals have lower incidences of side effects, adverse effects, and drug interactions as compared to both complementary medicines and conventional pharmaceutical.

Wang *et al.* 2020, carried out review research and they found out that Resveratrol (3,5,4'-trihydroxy-trans-stilbene) Spirulina (Arthrospira platensis) are nutraceutical with several proposed health benefits, including cardio protection, antimetabolic syndrome, and antiatherogenic effects. Both Nutraceuticals have hypolipidemic and antihypertensive properties which have potential therapeutic effects on several cardiovascular diseases.

Quiara *et al.* 2019 found out that the nutraceuticals act not only direct by antioxidant or anti-inflammatory properties but also indirectly, via modulation on various physiological pathways. A lot of the nutraceuticals that was described, such as oil extracts, plants, fruits and vegetables as well as botanical extracts, have shown beneficial effects on the cardiovascular system through substances such as phenolic compounds or polyphenols, lycopene and flavonoids. Nutraceutical supplementation and their intake could improve blood pressure control and must be considered strategic management aimed at preventing hypertension, when considering its benefits and low costs.

Silpi *et al*. 2019 found that herbs could be better options to formulate as nutraceuticals, as herbs have variety of therapeutic values such as immunity booster, antidiabetic, anticancer, antimicrobial, and gastroprotective. Several nutraceuticals are described based on their availability as food, chemical nature, and mechanism of action.

Vitamins, garlic, lycopene and tomato have already been shown to be able to reduce the blood pressure and prevent or delay cardiovascular diseases concluded by Alves *et al.* 2019.

Sajal *et.al,* (2018) carried out Literature searches on Prevention of Cardiovascular Diseases with anti-inflammatory and anti-Oxidant Nutraceuticals and herbal products: An Overview of Pre-clinical and clinical studies concluded that nutraceuticals along with healthy lifestyle, dietary habits, and regular physical activity possess enormous health benefits and their interventions can be highly beneficial in the prevention/reduction of CVDs and related disorders such as atherosclerosis, hypertension, heart attack and stroke.

Fruits contain unique active ingredients, having tremendous nutraceutical significances. Apart from the major fruits, minor fruits also have tremendous potentiality of being exploited as sources of nutraceuticals, since these fruits are used in traditional medicinal systems from time immemorial by Dutt *et al.* (2017)

Bozena *et al.* (2017) suggests that the application of nutraceuticals have the potential to increase the effectiveness of therapy (as well as to reduce the residual risk). Many of the nutraceuticals investigated for the prevention and treatment of CVD are well tolerated in patients.

Ahmed *et al.* (2012) conducted research on Hypoglycemic and antilipidemic properties of kombucha tea in alloxan-induced diabetic rats. Alloxan diabetic rats were orally supplied with kombucha and black tea at a dose of 5 mL/kg body weight per day for 30 days, fasted overnight, and sacrificed on the 31st day of the experiment. Their bloods were collected and submitted to various biochemical measurements, such as blood glucose, cholesterol, triglcerides, lipase, activities. The findings revealed that, compared to black tea, kombucha tea was a better inhibitor of α-amylase and lipase activities in the plasma and pancreas and a better suppressor of increased blood glucose levels. Interestingly, kombucha was noted to induce a marked delay in the absorption of LDL-cholesterol and triglycerides and a significant increase in HDL-cholesterol.

Blondeau *et al.,* 2011 conducted research on Nutraceuticals for stroke protection: A focus on α-linolenic omega-3 fatty acid and reported ALA supplementation by modification of the daily diet

prevented MCAO-induced mortality and cerebral damage in animal cerebral ischemia models, essentially evading the problem of delivery to the brain, which has normally to be addressed for chemical drugs. Inclusion of omega-3 prophylactically in the diet may induce a preconditioning effect, circumventing what is probably the major barrier in the field, which is timely delivery of a therapeutic ('time is brain').

Eman *et al.* (2011) carried out review research to examine the impact of functional foods in relation to the development and progression of CVD. Researcher found out that Epidemiological and clinical studies indicate that the risk of CVD is reduced by a diet rich in fruits, vegetables, unrefined grains, fish and low-fat dairy products, and low in saturated fats and sodium. Other foods such as mono and polyunsaturated fats, brans, nuts, plant sterols, and soy proteins have all been shown to have a favorable effect on lipid profile and blood pressure.

Penny *et al.* (2004) suggested that CVD risk reduction can be achieved by the long-term consumption of diets consistent with the AHA (American Heart Association) Dietary Guidelines;1 the long-term maintenance of a healthy body weight through balancing energy intake with regular physical activity; and the attainment of desirable blood cholesterol and lipoprotein profiles and blood pressure levels.

Methodology

The present study will be conducted in **four systematic phases**, each designed to fulfill specific objectives of the research project: ***"Development of Region-Specific Therapeutic Foods and Its Effect on Lipid Profile of CVD Subjects."*** The study adopts a mixed-method approach combining product development, clinical screening, intervention, and statistical analysis.

Phase I – Standardization of Nutraceutical Product: This phase focuses on the development and standardization of a region-specific functional food product intended for therapeutic use in individuals at risk of cardiovascular disease (CVD). The steps are as follows:

1. **Identification and Documentation of Region-Specific Anti-Lipidemic Foods**
   A comprehensive **review of scientific literature** along with **field-based dietary surveys** in Vijayapura city will be conducted to identify traditional foods known for their **hypolipidemic, antioxidant, or cardio-protective properties**. Foods will be selected based on criteria including nutrient profile, bioactive compounds, local availability, and cultural acceptance.

2. **Formulation and Standardization of the Therapeutic Product** using the identified ingredients, therapeutic food formulations (such as biscuits, health mixes, or snack items) will be developed. The **formulation trials** will involve multiple combinations and will undergo **sensory evaluation** using a 9-point hedonic scale to finalize the most acceptable version.
3. **Nutrient Composition and Antioxidant Analysis**
   The finalized therapeutic product will be analyzed for:

   1. Proximate composition (moisture, fat, protein, fiber, ash, carbohydrates by AOAC method)
   2. Antioxidant profile (e.g., vitamin C, vitamin E, total polyphenols, flavonoids)
   3. Bioactive compounds relevant to lipid-lowering functions

4. **SensoryEvaluation**
   Semi-trained panelists will evaluate the developed product for sensory attributes such as appearance, taste, texture, mouthfeel, and overall acceptability. **Acceptability index** will be calculated for each trial to determine consumer preference.

Phase II – Screening and Data Collection

This phase focuses on identifying individuals at risk of developing CVD using both clinical and lifestyle parameters. The participants will be screened based on **modifiable and non-modifiable risk factors**, with assistance from medical professionals.

Screening Parameters Include:

Risk Factor	**Tools/Method**
1. ACC/AHA Cardiovascular Risk Calculator	Standard risk scoring tool
2. Age and Gender	Pre-tested structured questionnaire
3. Family History of CVD	Questionnaire
4. Body Mass Index (BMI)	Height & Weight (Anthropometric Measurement)
5. Blood Pressure	Digital BP Monitor
6. Blood Lipid Profile	Biochemical blood tests (TC, LDL, HDL, TG)
7. Smoking and Alcohol Habits	Lifestyle questionnaire
8. Physical Activity Level	Questionnaire + Pedometer/Accelerometer (if feasible)
9. Dietary Intake	24-Hour Dietary Recall (Multiple Days)
10. Stress and Lifestyle Score	Lifestyle Assessment Questionnaire

Additional Information Collected:

- Socio-demographic data
- Medical history
- Occupational and lifestyle factors
- Pre-intervention nutrition knowledge

This comprehensive baseline dataset will help in identifying 70 individuals with high CVD risk for inclusion in the intervention study.

Phase III – Intervention Phase

Before beginning this phase, **ethical clearance** will be obtained from the Institutional Ethics Committee (IEC). **Informed consent** will be taken from all selected participants. Subjects will be divided into two groups based on their willingness to participate in the intervention.

1. Experimental Group (n = 35)

Participants in this group will:

- Undergo a baseline assessment (blood lipid profile, anthropometry, dietary patterns, and nutrition knowledge).
- Receive **nutritional intervention** in the form of the **standardized therapeutic food product**.
- Be provided with **IEC-based counseling sessions** focused on diet, physical activity, and lifestyle modification.
- Receive monthly follow-up and **blood lipid profile assessments at baseline and at the end of 4 months**.
- Have their anthropometric data monitored monthly.

2. Control Group (n = 35)

This group will not receive any nutritional product or education intervention. However:

- They will continue with **routine medical treatment and advice from their physicians**.
- Baseline and final assessments (anthropometry, dietary patterns, and lipid profile) will be recorded similarly to the experimental group.

Phase IV – Data Analysis and Report Writing

- **Data Analysis** Data collected from both groups will be statistically analyzed using appropriate tools such as:
- **Paired t-tests** for intra-group comparisons (pre vs. post)
- **Independent t-tests/ANOVA** for inter-group comparisons
- **Descriptive statistics** (mean, SD) for profile summaries
- **Correlation or regression** if needed to assess the relationship between dietary/lifestyle factors and lipid outcomes

- **Interpretation and Reporting**

- The findings will be interpreted to assess the **effectiveness of the therapeutic food product** and the **impact of IEC intervention**.
- A final report will be compiled and prepared for submission to the university and for **scientific publication**, targeting nutrition, food science, or public health journals.

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